IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

UNIVERSITY OF VIRGINIA PATENT FOUNDATION, Plaintiff and Counterclaim-Defendant, v. GENERAL ELECTRIC COMPANY d/b/a GE HEALTHCARE, Defendant and Counterclaimant.	CASE NO.: 3:08-cv-00025-nkm

DEFENDANT GENERAL ELECTRIC COMPANY'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INTERVENING RIGHTS

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PRELIMINARY STATEMENT

General Electric Company ("GE") submits this Memorandum in support of its motion for summary judgment of intervening rights for reexamined U.S. Patent No. 5,245,282 ("the '282 patent"). The Court previously granted GE partial summary judgment of no liability prior to the issuance of the reexamination certificate under 35 U.S.C. § 252 ¶1. (Dkt. No. 159.) The present motion addresses liability in the post-reexamination period, which is barred by both absolute and equitable intervening rights as codified in 35 U.S.C. § 252 ¶2. GE is entitled to absolute intervening rights because it made all of the accused pulse sequence applications long before the issuance of the '282 reexamination certificate. Furthermore, the Court should grant GE equitable intervening rights based on GE's substantial preparation, investments and business commitments made prior to the issuance of the '282 reexamination certificate.

GE's earlier motion for partial summary judgment addressed the scope of the '282 patent and the changes made by plaintiff University of Virginia Patent Foundation (the "Patent Foundation") during reexamination. The present motion focuses on GE's products, rather than on the '282 patent. The Patent Act provides intervening rights to protect GE's future sales of its products innocently developed, made and sold while the claims of the original '282 patent remained invalid. Here, those products are pulse sequence applications made by GE for use on its magnetic resonance imaging ("MRI") systems.

As this Court held, the claims of the original '282 patent that issued on September 14, 1993 remained invalid until at least the issuance of the '282 reexamination certificate on May 4, 2010. During the 16 years when the Patent Foundation chose not to correct its invalid claims, GE actively invested in developing pulse sequence applications for use in MRI systems. Physicians learned to use and rely on GE's pulse sequence applications to diagnose injury and disease. Because GE's pulse sequence applications were made years before – in one case, 14

years before – the reexamined claims issued on May 4, 2010, GE is entitled to absolute intervening rights.

Furthermore, to the extent there is any question as to whether GE could be potentially liable for other activities under the reexamined claims of the ’282 patent, GE is also entitled to equitable intervening rights. There can be no dispute that the making of pulse sequence applications for MRI required substantial preparation and investment. Developing pulse sequence applications required scientific research, thorough software application design, programming and testing, and clinical evaluation and validation. These procedures are not optional, but rather are mandated by federal regulations on medical devices under the authority of the U.S. Food and Drug Administration. In order to participate in the business of pulse sequence applications, a company like GE must be willing to make substantial investments and business commitments long before the applications are completed and can be sold for use in the diagnosis of patients.

When the Patent Foundation brought this lawsuit, GE promptly sought *ex parte* reexamination of the original ’282 patent – before the Patent Foundation had served its Disclosure of Asserted Claims and Infringement Contentions. The USPTO agreed that the prior art identified by GE invalidated the claims of the original ’282 patent, and the Patent Foundation then disclaimed the original claims in order to obtain the narrowed, reexamined claims. At any time before that, the Patent Foundation could have sought to narrow the overbroad claims of the original ’282 patent. However, it chose not to do so until after the USPTO had rejected the original ’282 patent claims at GE’s request. In these circumstances, the Patent Act authorizes equitable intervening rights in order to protect GE’s preparation, investments made and business commitments.

FACTUAL BACKGROUND

A. The Reexamined '282 Patent Claims a Method for Using a Pulse Sequence in Magnetic Resonance Imaging.

Claim 1 of the reexamined '282 patent recites "[i]n a method for producing a set of magnetic resonance three-dimensional image data, a preparation-acquisition-recovery pulse sequence cycle comprising…" (Dkt. No. 102–2 at 22:7–9.) All the other, dependent claims are directed to the same method. The reexamined '282 patent does not purport to claim MRI scanning or imaging hardware, which GE and other industry leaders have supplied to doctors and hospitals for decades.

An MRI system produces images in part by repeating a pulse sequence cycle. (*See id*. at 1:17-38 (describing use of pulse sequences in MRI).) An MRI scanner applies a strong constant magnetic field to the patient, then executes a pre-programmed pulse sequence – a series of radiofrequency pulses, changes in the magnetic field, and time delays – during which the scanner collects the electronic data that is ultimately converted into an image. (*See* Dkt. No. 158, Mem. Op. at 2 (citing references).) In an MRI system, a pulse sequence is programmed in a software application on a computer used to control the scanner. (Declaration of Ersin Bayram at ¶3.) It is only by the execution of the appropriate software application that an MRI scanner will perform a pulse sequence of the kind claimed by the '282 patent. (*Id*.)

B. The Patent Foundation's Allegations Are Directed to Specific GE Pulse Sequence Applications Made and Sold Before the Issuance of the '282 Reexamination Certificate.

On June 5, 2009, the Patent Foundation served its Disclosure of Asserted Claims and Infringement Contentions ("Infringement Contentions"). (Dkt. Nos. 173-1 & 173-2.) The Patent Foundation identified as accused instrumentalities some 12 "sequence techniques" used in various GE MRI systems. (Dkt. No. 173-1 at 2.) To the extent these sequence techniques have

been made or sold by GE, they have been programmed into specific pulse sequence applications. (Decl. at ¶5.) All of the pulse sequence applications incorporating the accused sequence techniques named in the June 5, 2009 Infringement Contentions were made and sold by GE before May 4, 2010. (*Id.*) In fact, one of the pulse sequence applications was made and sold as early as 1994. (*Id*. at ¶9.)

C. **The Patent Foundation Substantively Changed the Scope of All of the Original '282 Patent Claims During Reexamination to Overcome Prior Art Submitted by GE.**

On March 13, 2009, GE filed a request with the USPTO for *ex parte* reexamination of the original '282 patent in light of a number of prior art references known to GE. (Dkt. No. 102-3.) On May 6, 2009, the USPTO granted GE's request for reexamination, finding several substantial new questions of patentability. (Dkt. No. 102-4.) On October 1, 2009, the USPTO rejected all the claims subject to reexamination as anticipated or obvious in light of the prior art submitted by GE. (Dkt. No. 102-5.)

On November 30, 2009, the Patent Foundation filed an Amendment to the claims of the '282 patent under 37 C.F.R. § 1.111 and § 1.550. (Dkt. No. 102-8.) The Patent Foundation then argued that, in light of its newly-disclosed position on the scope of its claims, it could overcome the Examiner's invalidity rejections based on GE's prior art. (*See, e.g., id.* at 30.) On May 4, 2010, the USPTO issued a Reexamination Certificate for the '282 patent. (Dkt. No. 102-11.)

On November 9, 2010 this Court issued its Memorandum Opinion granting GE partial summary judgment of no liability prior to the issuance of the '282 reexamination certificate based on the Court's ruling that the Patent Foundation had substantively narrowed the scope of the '282 patent claims during reexamination. (*See* Dkt. No. 158, Mem. Op. at 47.) On February 8, 2011, the Court affirmed its ruling. (Dkt. No. 176.)

D. **GE Complies with Federal Regulations Mandating Strict Control of the Design, Development, Deployment and Modification of GE's Pulse Sequence Applications.**

GE does not, and under federal regulations may not, revise the functionality of its pulse sequence applications without first completing thorough procedures to comply with U.S. Food and Drug Administration ("FDA") requirements. (Decl. at ¶¶12-18.) Pursuant to 21 U.S.C. § 360c(a)(1)(B), the FDA classifies MRI systems as Class II medical devices. *See* 21 CFR § 892.1000 (defining and classifying a magnetic resonance diagnostic device). The FDA mandates a rigorous quality management system for Class II medical devices. 21 CFR § 820.20. Among the numerous requirements imposed by the FDA, GE must verify and validate the design of the pulse sequence application, "includ[ing] software validation and risk analysis, where appropriate." *Id*. at § 820.30(f) & (g). Furthermore, GE is required to "establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation." *Id.* at § 820.30(i).

GE complies with these and other federal regulations by imposing a strict quality management system on its pulse sequence applications. (Decl. at ¶12.) In particular, before any pulse sequence application is offered for commercial release, GE requires the following be completed, with a formal review and approval: (1) a design inputs plan; (2) a design output plan, (3) a design verification plan, (4) a design transfer plan, and (5) a design validation plan. (*Id*. at ¶13.) GE's design verification process for pulse sequence applications includes test procedures to determine whether the product meets specifications; GE's design validation process includes procedures to validate the product's usability with representative users. (*Id*. at ¶¶14 & 15.) Each step in GE's quality management system is carried out by several GE personnel with assigned responsibilities, including a Lead System Designer, Program Manager, Quality Assurance representative, and others. (*Id*. at ¶16.) The completion of the steps generally requires between

six and 18 months. (*Id*. at ¶17.) The FDA periodically inspects GE's quality management system. (*Id*. at ¶18.)

E. **GE Prays for Declaratory Judgment of Intervening Rights.**

On February 14, 2011, GE filed and served its Supplemental Answer and Affirmative Defenses and Supplemental Counterclaims, praying that the Court find and declare that GE and the customers using its products or services are entitled to absolute and equitable intervening rights for the reexamined '282 patent. (Dkt. No. 179.)

ARGUMENT

I. SUMMARY JUDGMENT IS APPROPRIATE.

Summary judgment in a patent case, as in any other case, is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Warner Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39, n.8 (1997). Once the moving party meets the requirement of Rule 56 by showing that no genuine issue of material fact remains, the burden shifts to the party resisting the motion, who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). Here, the Patent Foundation cannot point to a single disputed issue for trial because the statutory defense of intervening rights is based on indisputable evidence and presents purely legal issues for the Court to decide. Accordingly, summary judgment of intervening rights is appropriate. *See Engineered Data Prods., Inc. v. GBS Corp.*, 506 F. Supp. 2d 461 (D. Colo. 2007) (granting summary judgment of intervening rights); *Linear Tech. Corp. v. Micrel, Inc.*, 524 F. Supp. 2d 1147 (N.D. Cal. 2005) (same).

II. GE IS ENTITLED TO ABSOLUTE INTERVENING RIGHTS.

A. The Patent Act Confers on GE Absolute Intervening Rights to Use and Sell Pulse Sequence Applications that Were Made, Used, or Sold Before the Issuance of the '282 Reexamination Certificate.

All of GE's pulse sequence applications that may use any of the techniques accused in the Patent Foundation's June 5, 2009 Infringement Contentions were made, used and sold before the May 4, 2010 issuance of the '282 reexamination certificate. (Decl. at ¶5.) Therefore, GE is entitled to absolute intervening rights under the Patent Act.

Title 35 U.S.C. § 307(b) provides the same protections for intervening rights for reexamined patents as codified in 35 U.S.C. § 252 ¶2 for reissued patents. *See Bloom Eng'g Co., Inc. v. North Am. Mfg. Co., Inc.*, 129 F.3d 1247, 1249 (Fed. Cir. 1997). As the Federal Circuit has explained:

> The first sentence [of § 252 ¶2] defines "absolute" intervening rights. This sentence provides an accused infringer with the absolute right to use or sell a product that was made, used, or purchased before the grant of the reissue patent as long as this activity does not infringe a claim of the reissue patent that was in the original patent. This right is absolute.

BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 1 F.3d 1214, 1220-21 (Fed. Cir. 1993). The defense of absolute intervening rights protects a potential infringer from liability for infringement of the substantively changed claims in a reexamination certificate, *i.e.*, the period *after* issuance of the reexamination certificate. *See Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1346 (Fed. Cir. 1998) (citing *Bloom Eng'g Co.*, 129 F.3d at 1249-50). Intervening rights are available for narrowing changes to the patent's scope as well as broadening ones. *See Bloom Eng'g Co.*, 129 F.3d at 1250-51 (holding that a narrowing change during reexamination satisfied the requirements of 35 U.S.C. § 307(b)). In this case, the Court determined that the Patent Foundation substantively changed all the claims of the original '282 patent during reexamination. (Dkt. No. 158, Mem. Op. at 47.) Therefore, the Patent Act confers on GE absolute intervening rights for all claims of the reexamined '282 patent.

B. **The Accused Pulse Sequence Applications Were Made, Used and Sold Before May 4, 2010.**

It is undisputed that all of the pulse sequence applications that may incorporate the accused sequence techniques identified in the June 5, 2009 Infringement Contentions were made and sold by GE before May 4, 2010. (Decl. at ¶5.) As a matter of law, therefore, GE is entitled to absolute intervening rights. *See Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 756 F.2d 1574, 1579-81 (Fed. Cir. 1985) (granting intervening rights for products already made at time of reissue); *Arcade Inc. v. Minn. Mining & Mfg. Co.*, 24 U.S.P.Q.2d 1578, 1592 (E.D. Tenn. 1991), *aff'd mem.*, 1 F.3d 1253 (Fed. Cir. 1993) (same).

III. GE IS ENTITLED TO EQUITABLE INTERVENING RIGHTS BASED ON ITS SUBSTANTIAL PREPARATION, INVESTMENTS MADE AND BUSINESS COMMENCED IN GOOD FAITH.

To the extent there is any doubt as to whether GE's future actions after the issuance of the reexamination certificate are fully protected against claims of infringement, the Court should grant GE equitable intervening rights. GE expended its time and resources to research, design, develop, test, validate and commercially release the pulse sequence applications that GE correctly believed to be unencumbered by any valid patent claims prior to the issuance of the '282 reexamination certificate. GE's good faith investments in its medical technology mandate a finding that GE is entitled to equitable intervening rights.

The second sentence of 35 U.S.C § 252 ¶2 sets forth equitable intervening rights, which shield additional products from liability "for the protection of investments made or business commenced." "The second sentence [of § 252 ¶2] permits the continued manufacture, use, or sale of *additional products* covered by the reissue patent when the defendant made, purchased, or used identical products, or made substantial preparations to make, use, or sell identical products, before the reissue date." *BIC Leisure*, 1 F.3d at 1221 (emphasis added). Title 35 U.S.C.

§ 307(b) provides for the same rights after reexamination. *See Richardson-Vicks, Inc. v. UpJohn Co.*, No. 93-556, 1996 WL 31209, at *7 (D. Del. Jan. 17, 1996) (granting equitable intervening rights under § 307(b)). The reason for equitable intervening rights is that "a person should be able to make business decisions secure in the knowledge that those actions which fall outside the original patent claims are protected." *Seattle Box Co.*, 756 F.2d at 1579.

In determining whether an accused infringer is entitled to equitable intervening rights, a court should consider the following factors: (1) whether substantial preparation was made before the reissue/reexamination; (2) whether there were existing orders or contracts at the time of the reissue/reexamination; and (3) whether noninfringing goods can be manufactured from the inventory used to manufacture the infringing product and the cost of conversion. *Id.* at 1579-80. Because the Section 252 ¶2 recognizes that this determination is an equitable one, a court may also consider the degree of good faith exercised by the accused infringer. *See id.*; *Richardson-Vicks*, 1996 WL 31209 at *7 (finding good faith reliance on the invalidity of a patent to be demonstrated by a successful request for reexamination.) Here, all of these factors strongly favor the grant of equitable intervening rights to GE.

A. **GE Made Substantial Preparation to Sell Its Pulse Sequence Applications and Had Existing Contracts Before May 4, 2010.**

Before the May 4, 2010 issuance of the reexamined '282 patent, GE made "substantial preparation" for the continued manufacture, use, and sale of its pulse sequence applications alleged to infringe the reexamined '282 patent. *See* 35 U.S.C. § 307(b). Indeed, all of GE's accused pulse sequence applications were made before May 4, 2010, and one application has been sold since 1994. (Decl. at ¶¶5-9.) However, for the avoidance of doubt about potential future liability for GE's pulse sequence applications, it is also clear that GE made "substantial preparation" for continued manufacture, use, and sale of its accused pulse sequence applications.

See Richardson-Vicks, 1996 WL 31209 at *7 (finding "it really cannot be disputed" that defendant's investment in the FDA approval process "entails a substantial investment which has substantial value, all of which is nonfungible in nature").

There can be no dispute that GE's accused pulse sequence applications required investment of substantial time and resources for research, design, development and verification, as well as clinical validation and regulatory compliance. (Decl. at ¶¶12-18.) By its nature, medical software requires heavy up-front investments in time and effort before a product is made for release. Furthermore, the strict procedures mandated by the FDA require that GE invest "substantial preparation" prior to any commercial release. The procedures required by the FDA generally require six to 18 months to complete. (*Id*. at ¶17.)

GE continuously sold pulse sequence applications throughout the period before and after May 4, 2010 (i.e., GE had existing contracts). (*Id*. at ¶¶5-8.) The first two factors weigh heavily in GE's favor.

B. **The Pulse Sequence Applications Cannot Be Converted to Other Uses.**

GE does not, and under federal regulations may not, modify the functionality of its pulse sequence applications at will. (*Id*. at ¶¶12-18.) Thus, GE's pulse sequence applications are not like, for example, word processing applications or other non-regulated software that can be revised at the manufacturer's convenience. Moreover, software applications are by their nature unlike physical goods, where inventory can often be put to other, nonaccused uses or sold to others who might dispose of the physical inventory by nonaccused uses. GE's pulse sequence applications cannot be converted to other uses. The third factor also weighs in GE's favor.

C. **The USPTO's Rejection of the Original '282 Patent Claims on Reexamination Confirmed GE's Good Faith Belief Those Claims Were Invalid.**

GE's actions both before and after the issuance of the '282 reexamination certificate were taken in good faith, as demonstrated by its successful request for reexamination that ultimately led to the invalidating of the original '282 patent claims. *See Richardson-Vicks*, 1996 WL 31209 at *7 (finding good faith reliance on the invalidity of a patent based on a successful request for reexamination that led to patentee cancelling claims in order to obtain issuance of a reexamination certificate). When the Patent Foundation brought this lawsuit, GE promptly sought and obtained *ex parte* reexamination of the original '282 patent claims. (Dkt. Nos. 102-3 & 102-4.) The USPTO agreed that the prior art cited by GE raised several "substantial new questions of patentability." (Dkt. No. 102-4.) The USPTO then rejected all of the reexamined claims as invalid in light of the prior art. (Dkt. No. 102-5.) Moreover, as this Court found in its Memorandum Opinion granting GE partial summary judgment, Dkt. No. 158, the Patent Foundation surrendered the original '282 claims by its narrowing arguments during reexamination. GE's belief that the original '282 patent claims were invalid was in good faith, and in fact was objectively correct. *See Bloom Eng'g Co.*, 129 F.3d at 1249 ("the making of substantive changes in the claims is treated as an irrebuttable presumption that the original claims were materially flawed").

In contrast, the Patent Foundation has no excuse for its delay in addressing the invalidity of the original '282 patent claims. Prior to May 4, 2010, all the claims of the original patent were fatally flawed due to the attempt to claim broader scope than the patent applicants were entitled to under the Patent Act. Although the Patent Foundation could have, and should have, sought to correct this error, it elected to do nothing until over 16 years after the '282 patent issued. During that 16 year period, while all of the original claims of the '282 patent remained

invalid, GE invested in research, development, clinical evaluation and regulatory compliance for the pulse sequence applications that the Patent Foundation has now accused of infringement.

Because the Patent Foundation delayed 16 years to address the invalidity of its patent, while GE acted in good faith and was proved correct, the fourth factor favors GE. Accordingly, the Court should grant GE equitable intervening rights as authorized by 35 U.S.C. § 252 ¶2 for "the protection of investments made or business commenced" before the May 4, 2010 issuance of the reexamined '282 patent.

CONCLUSION

For the foregoing reasons, GE requests that the Court grant its motion for summary judgment of intervening rights and enter final judgment for GE and against the Patent Foundation on all claims for relief in the Patent Foundation's Amended Complaint.

DATED: March 4, 2011

Respectfully Submitted,

By: /s/ Carl G. Anderson

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CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2011, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send electronic notification of such filing to the address listed below:

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